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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/594,613	12/13/2006	Toshiya Kai	NPR-193	5015
20374 7590 08/11/2008 KUBOVCIK & KUBOVCIK SUITE 1105 1215 SOUTH CLARK STREET ARLINGTON, VA 22202				
EXAMINER ARNOLD, ERNST V				
ART UNIT		PAPER NUMBER		
1616				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/594,613

Applicant(s)

KAI ET AL.

Examiner

ERNST V. ARNOLD

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF 298)
Paper No(s)/Mail Date ____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____

DETAILED ACTION

Claims 1-9 are pending and under examination.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Kai et al. (US 2002/0061338).

Kai et al. disclose a solid preparation for dialysis and methods of preparing a double preparation type sodium bicarbonate solid preparation (Abstract and claims 1-9). The first composition has core particles including **sodium chloride** and a coating layer of one or more electrolytes and the second composition comprises a sugar and an acid (Abstract). The first composition with the core particles of sodium chloride coated with an electrolyte such as **calcium chloride** has an average particle diameter of the granules is 300 to 1700 microns and is mixed with the second composition (claims 1

and 6). The specification discloses a limited list of acids including acetic acid, hydrochloric acid, lactic acid, **citric acid** and oxalic acid and the like ([0034]). Thus a single composition comprising core particles coated with an electrolyte and an acid is disclosed. Kai et al. disclose a sodium bicarbonate solid preparation in combination with the composition of claim 1 (claim 7) which anticipates instant claims 1-3, 6 and 7 because the acid can be hydrochloric or lactic or citric or oxalic acid. Since the ingredients are exactly the same as instantly claimed then a plurality of them would inherently be bound together and the organic acid would be uniformly distributed within the particles.

Kai et al. disclose two different methods of making the solid preparation. In the first method (claim 8) Kai et al. disclose spraying an aqueous solution of electrolyte containing, for example, magnesium chloride, unto core particles of sodium chloride and then drying and a second step of spraying core particles of a sugar to obtain a second composition and a third step of mixing the first and second composition with an acid to obtain a solid preparation.

Kai et al. disclose a second method in claim 9 the difference being that the first composition is mixed with an acid first and then mixed with the second composition comprising the sugar to obtain a solid preparation for dialysis. These method steps anticipate instant claims 4, 5, 8 and 9 because Kai et al. disclose in the specification that the acid can be solid citric acid, which by the nature of it being a solid, will also be a particle ([0034]). It is the Examiner's position that since the materials are the same and the method steps of spraying and drying are the same as instantly claimed then the

method of Kai et al. inherently granulates the material. Evidence of granulation is provided in claim 6.

Claim Rejections - 35 USC § 102

Claims 1-3, 6 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Kai et al. (US 6,464,977).

Kai et al. disclose a sodium bicarbonate solid preparation for dialysis comprising the solid preparation of claim 1 and a solid preparation containing sodium bicarbonate (claim 4). In claim 1, Kai et al. disclose a solid preparation of comprising a mixture of core particles of sodium chloride coated with one or more electrolytes such as magnesium chloride and particles of a second composition and an acid (claim 1). The acid can be acetic acid, hydrochloric acid, lactic acid, or citric acid or oxalic acid (claim 2 and column 5, lines 20-27). The granulated particle size is 300 to 1700 microns (claim 3). Since the ingredients are exactly the same as instantly claimed then a plurality of them would inherently be bound together and the organic acid would be uniformly distributed within the particles. Therefore, the Examiner concludes that instant claims 1-3, 6 and 7 are anticipated by Kai et al.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kai et al. (US 2002/0061338) in view of Kuzuya et al. (US 5,858,645).

Applicant claims a solid pharmaceutical preparation for dialysis.

Determination of the scope and content of the prior art

(MPEP 2141.01)

The reference of Kai et al. is discussed in detail above and that discussion is hereby incorporated by reference.

Kuzuya et al. teach organic acids such as lactic acid, gluconic acid, pyruvic acid (claim 2); oxaloacetic acid, maleic acid, malic acid, tartaric acid (claim 4) and citric acid (claim 6).

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

1. The difference between the instant application and Kai et al. is that Kai et al. do not expressly teach tartaric, maleic, ascorbic, oxaloacetic, gluconic, isocitric, malic and pyruvic acid in the composition for dialysis. This deficiency in Kai et al. is cured by the teachings of Kuzuya et al.

Finding of prima facie obviousness

Rational and Motivation (MPEP 2142-2143)

1. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to add tartaric, maleic, ascorbic, oxaloacetic, gluconic, isocitric, malic and pyruvic acid, as suggested by Kuzuya et al., to the composition of Kai et al. and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Kai et al. suggest other acids and Kai et al. teach that these are known organic acids. Furthermore, isocitrate is a homolog of citric acid and would be expected to have the similar properties of citric acid in the absence of evidence to the contrary.

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ernst V. Arnold whose telephone number is 571-272-8509. The examiner can normally be reached on M-F (6:15 am-3:45 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1616

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Ernst V Arnold/
Examiner, Art Unit 1616